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SUBJECT TO PROTECTIVE ORDER

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

APOTEX, INC., Plaintiff, v. CEPHALON, INC., et al. Defendants.	)	CIVIL ACTION No. 06-2768 MSG

DEFENDANT CEPHALON, INC.'S PRE-TRIAL MEMORANDUM – PATENT CASE (INFRINGEMENT)

(Redacted Version)

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Pursuant to Local Rule 16.1(c) and the Court's Final Pre-Trial Order For Patent Infringement Trial dated June 1, 2011, defendant Cephalon, Inc. ("Cephalon") respectfully submits its Pre-Trial Memorandum for the infringement phase of the bifurcated patent action concerning Cephalon's '516 Patent.[1]

NATURE OF THE ACTION AND JURISDICTION

Plaintiff Apotex, Inc. ("Apotex") filed this action alleging declaratory judgment claims relating to Cephalon's U.S. Reissue Patent No. 37,516 ("the '516 Patent") and U.S. Patent No. 7,297,346 ("'346 Patent") and antitrust claims challenging settlement agreements between Cephalon and certain generic companies. Cephalon asserted a counterclaim for infringement of the '516 Patent by Apotex's submission of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking permission to market a generic version of Cephalon's Provigil®. Apotex alleges that its proposed generic modafinil product does not infringe Cephalon's '516 Patent and Cephalon asserts that Apotex does infringe.[2]

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[1] Pursuant to the June 1, 2011 Order, the parties are to exchange lists of exhibits and copies on July 1, 2011, rather than listing them in this Pre-Trial Memorandum.

[2] But for Apotex's lack of standing, this Court would have subject matter jurisdiction over Apotex's '516 Patent claims pursuant to 28 U.S.C. §§ 1331, 1338(a), 1400(b), 2201, and 2202. *See* Cephalon's Pre-Trial Mem. at 25-29, Dkt. No. 405; Cephalon's Post-Trial Br. at 38-39, Dkt. No. 459; Cephalon's Opp. to Apotex's Mot. For Leave to File a Notice of FDA Approval at 2-5, Dkt. No. 467.

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STATEMENT OF FACTS

I. THE '516 PATENT

Cephalon is the owner by assignment of the '516 Patent, which is listed as covering Cephalon's Provigil® product in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book). The '516 Patent describes and claims pharmaceutical compositions containing modafinil of a defined particle size, wherein at least about 95% of the modafinil particles have a diameter of less than about 200 microns (μm).[3] The patent describes numerous types of pharmaceutical compositions in which modafinil has the defined particle size range, as well as ways to prepare such compositions. For example, the patent identifies milling as an approach that can be utilized to achieve the claimed particle size distribution within these compositions. It also explicitly teaches that unprocessed active pharmaceutical ingredient ("API") of undefined size can be milled to make it smaller, and then measured by sieving; if it is still too large, it can be milled until the particle size meets the claimed range limitations. Nowhere in the '516 Patent does it state that testing for infringement is limited only to testing particle size of the "bulk" API before manufacturing the tablets. Accordingly, an accused product infringes the '516 Patent if the particle size of the modafinil in the finished dosage form falls with the claimed ranges of the patent.

II. INFRINGEMENT

On March 30, 2005, Apotex filed an ANDA with the FDA seeking to market a generic version of Provigil®. *See* Apotex Complaint dated June 26, 2006, Dkt. No. 1, at ¶ 89. At that

[3] The Court's constructions of relevant terms from the asserted claims of the '516 Patent were provided in the Court's Memorandum Opinion of October 6, 2010 (Dkt. No. 335).

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time, Apotex certified to the FDA under Paragraph III of 21 U.S.C. § 355(j)(2)(A) that Apotex was *not* challenging the '516 Patent, and thus was not seeking to market its ANDA modafinil product until after the patent expired.

On March 9, 2006, Apotex notified Cephalon that it had converted its Paragraph III certification to a Paragraph IV certification. In its Paragraph IV notice, Apotex asserted non-infringement of only claims 17 and 26 of the '516 Patent, directed to modafinil "salts" (which Apotex's proposed product allegedly does not have). At that time, Apotex did not assert that its product would not infringe the remaining 24 claims of the '516 Patent.

On June 26, 2006, Apotex filed the present declaratory judgment action. In its Complaint, Apotex alleged that the '516 Patent was invalid and unenforceable. As to infringement, Apotex made no allegation that its proposed product would not contain each and every claim element of claims 1-14 and 16 of the '516 Patent. (*See* Apotex Complaint of June 26, 2006, Dkt. No. 1.)

On August 10, 2009, three years after filing its original Complaint, and after the modafinil samples used by Apotex to conduct the testing described in its ANDA had expired, Apotex amended its Complaint to allege that its proposed generic modafinil product would not infringe any claims in Cephalon's '516 Patent. (*See* Apotex Complaint of August 10, 2009, Dkt. No. 149.) By waiting over four years between filing its modafinil ANDA and alleging non-infringement of asserted claims 1-14 and 16 of the '516 Patent, Apotex unfairly deprived Cephalon of the opportunity to test the unexpired modafinil API (and unexpired tablets made from that API) upon which the particle size specification in Apotex's ANDA was based.

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Apotex's non-infringement arguments rely on particle size measurements conducted by Apotex on now-expired bulk modafinil API. The evidence at trial will show that these Apotex measurements were made using non-representative samples, measured modafinil agglomerates (rather than individual modafinil particles),[4] and were designed by Apotex to overestimate modafinil particle size.

Furthermore, Apotex's ANDA, and the particle size specification upon which it is based, reports a particle size measurement [redacted]

[4] An agglomerate is a group of particles held together by relatively weak forces, which can be dispersed or deagglomerated by proper sample preparation techniques.

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[redacted] Although Cephalon requested production of Apotex's modafinil products, Apotex never produced samples of its Canadian product. Instead, Cephalon acquired a bottle of Apotex's 100 mg modafinil tablets sold in Canada.[5] Cephalon's experts isolated the modafinil particles from six random samples of these tablets (two tablets per sample), and analyzed the size of the isolated modafinil particles using a Hiac/Royco, the preferred instrument of the '516 Patent. The testing showed that, in three of the six Apotex samples, about 95% of the cumulative total of modafinil particles have a diameter less than about 200 microns ("about" 200 microns is defined as 180-220 microns).

Apotex still has never produced any samples of its Canadian tablets, which it is currently manufacturing and selling in Canada. Nor has it produced any particle size test results on its Canadian product [redacted] As a result of Apotex's failure to produce modafinil tablets (and API) for the Canadian market, Cephalon was put in the unfair position of having to obtain theses tablets through other channels. Nor can Apotex argue that infringement cannot be demonstrated by particle size testing on modafinil extracted from the Canadian tablets when it was Apotex that failed to produce the API from which those tablets are made.

[5] The sealed bottle contained Apotex Inc. Apo-Modafinil 100 mg modafinil tablets, 100 count, with markings of DIN 02285398, batch JL0614, expiration January 2012. Apotex has never denied producing a batch of modafinil tablets called JL0614.

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SPECIAL COMMENTS REGARDING LEGAL ISSUES

I. APOTEX'S PROPOSED PRODUCT INFRINGES THE '516 PATENT

Cephalon will prove at trial that the modafinil product that Apotex is likely to sell in the United States (in the event that its ANDA is approved by the FDA) would infringe Cephalon's '516 Patent. *See Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568 (Fed. Cir. 1997) ("an infringement inquiry [in an ANDA case is] focused on what is likely to be sold following FDA approval"). Cephalon's proof of infringement will consist of the results of particle size testing conducted by Cephalon's experts on Apotex's modafinil tablets as well as Apotex documents and deposition admissions from Apotex's witnesses.

A. LEGAL STANDARD

1. Act of Infringement

The statute governing the effect of a submission of an ANDA for approval to market a patented drug reads, in relevant part:

> It shall be an act of infringement to submit-(A) an application under [21 U.S.C. § 355(j)] or described in [21 U.S.C. § 355(b)(2)] for a drug claimed in a patent or the use of which is claimed in a patent ... if the purpose of such a submission is to obtain approval under [Title 21 of the United States Code] to engage in the commercial manufacture, use, or sale of a drug ... claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. § 271(e)(2). "[T]he statute requires an infringement inquiry focused on what is likely to be sold following FDA approval." *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568 (Fed. Cir. 1997).

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At trial, the Court must determine whether Apotex's ANDA product, if sold or used in the United States, would infringe the '516 Patent, either literally or under the doctrine of equivalents. *See Allergan, Inc. v. Alcon Laboratories, Inc.*, 324 F.3d 1322, 1331 (Fed. Cir. 2003) ("The only difference in the analysis of a traditional infringement claim and a claim of infringement under section 271(e)(2) is the timeframe under which the elements of infringement are considered."). The party asserting infringement need only prove infringement by a preponderance of the evidence. *Symbol Technologies, Inc. v. Opticon, Inc.*, 935 F.2d 1569, 1574 (Fed. Cir. 1991).

2. Definition of Infringement

Under 35 U.S.C. § 271, infringement occurs when one makes, uses, offers to sell, or sells any patented invention within the United States without authority to do so. Determining infringement entails two steps. *Solvay S.A. v. Honeywell Intern., Inc.*, 622 F.3d 1367, 1379 (Fed. Cir. 2010). First, the court determines the scope and meaning of the claims asserted to be infringed. *Id.* (*citing Markman v. Westview Instruments, Inc*., 52 F.3d 967, 976 (Fed. Cir. 1995)). Second, the court must compare the properly construed claims to the accused product or process. *Id.* at 1379.

If the accused product or process contains every element of the asserted claim, either literally or under the doctrine of equivalents, then it infringes. *General Electric Co. v. Sonosite Inc*., 568 F. Supp 983, 990 (Fed. Cir. 2008) (*citing Warner-Jenkinson Co. v. Hilton Davis Chem. Co*., 520 U.S. 17, 40 (1997)).

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3. Literal Infringement

In order for a Court to find infringement, Cephalon must show "the presence of every element or its substantial equivalent" in the accused product or process. *Lemelson v. United States*, 752 F.2d 1538, 1551 (Fed. Cir. 1985) (footnote omitted). When an accused product or process contains each and every element of an asserted claim precisely as construed, this is referred to as literal infringement. *Revolution Eyewear, Inc. v. Aspex Eyewear, Inc.*, 563 F.3d 1358, 1369 (Fed. Cir. 2009).

4. Doctrine of Equivalents

Under the doctrine of equivalents, infringement may be found even if an accused product or process is different from the claimed invention, provided that the difference is insubstantial. For example, if the accused product or process performs substantially the same function, in substantially the same way, to obtain substantially the same overall result as the claimed invention, then it infringes under the doctrine of equivalents. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co*., 520 U.S. 17, 38-40 (1997). To be an infringing equivalent, "the element substituted in the accused device for the element set forth in the claim must not be such as would substantially change the way in which the function of the claimed invention is performed." *Perkin-Elmer Corp. v. Westinghouse Elec. Corp.*, 822 F.2d 1528 (Fed. Cir. 1987).

5. Direct and Indirect Infringement

A patent may be infringed directly or indirectly, for example, by contributory infringement or inducement of infringement. *Dynacore Holdings Corp. v. U.S. Philips Corp*., 363 F.3d 1263, 1272 (Fed. Cir. 2004). Section 271(c) of title 35 provides that:

> [w]hoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

Under § 271(b), "whoever actively induces infringement of a patent shall be liable as an infringer." *See Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1363 (Fed. Cir. 2003) ("[t]o succeed on this theory, a plaintiff must prove that the defendants' actions induced infringing acts and that [they] knew or should have known [their] actions would induce actual infringement") (internal quotations and citations omitted).[6]

B. APOTEX'S PROPOSED PRODUCT LITERALLY INFRINGES CLAIMS 1-14 AND 16 OF THE '516 PATENT

The key disputed element of each of the asserted claims of the '516 Patent is whether Apotex's product meets the requirement that "at least about 95% of the cumulative total of modafinil particles in said composition have a diameter of less than about 200 microns (μm)." The Court has construed this claim term to mean "approximately 95% of the aggregate of the individual percent values for all measurable particles in the composition based on a volume distribution."

[6] It is undisputed that Apotex was aware of the '516 Patent when it submitted its ANDA and its Paragraph III and IV certifications to the FDA.

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1. Test Results On Tablets Identical to Apotex's Proposed ANDA Product Demonstrate Infringement

When discovery in the patent portion of the case began and Cephalon requested Apotex's unexpired modafinil product samples for testing, Apotex denied that it had such samples in its possession. Subsequent discovery established that Apotex's modafinil tablets sold in Canada [redacted] Nor have Apotex's experts conducted any particle size testing of their own on Apotex's Canadian product.

Cephalon obtained a bottle of Apotex modafinil tablets sold in Canada, and Cephalon's expert conducted particle size testing to measure the particle size of the modafinil in those tablets. Three of the six tablet samples showed average 95% cumulative values of 159, 200, and 201 microns. These values meet the particle size limitations of the '516 Patent, which requires that "at least about 95% of the cumulative total of modafinil particles…have a diameter of less than about 200 microns (μm)."[7] This evidence establishes infringement. *See, e.g., Embrex, Inc. v. Serv. Eng'g Corp.*, 216 F.3d 1343, 1353 (Fed. Cir. 2000) ("[T]he statute leaves no leeway to excuse infringement because the infringer only infringed a little . . . ."); *Bell Communications Research, Inc. v. Vitalink Communications Corp.*, 55 F.3d 615, 622 -623 (Fed. Cir. 1995) (noting principle that "an accused product that sometimes, but not always, embodies a claimed method nonetheless infringes"); *Paper Converting Machine Co. v. Magna-Graphics Corp.*, 745 F.2d 11,

[7] The '516 Patent defines the meaning of "about" as: "plus or minus approximately ten percent of the indicated value," so that "about 200 microns" means approximately 180 to 220 microns.

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20 (Fed. Cir. 1984) ("[I]mperfect practice of an invention does not avoid infringement."); *Laitram Corp. v. Cambridge Wire Cloth Co.*, 863 F.2d 855, 859 (Fed. Cir. 1989) ("[I]nefficient infringement is still infringement."); *see also Deuterium Corp. v. United States*, 19 Cl. Ct. 624, 631 (1990) ("[I]nfringement is not a question of degree.").[8]

In view of the plain language of the claims, which recite a "pharmaceutical composition," there is no basis for requiring infringement to be demonstrated by measuring the particle size distribution of the bulk API prior to formulation (as Apotex is expected to argue). Apotex's own expert admitted at the validity trial that the claims of the '516 Patent are directed to the particle size of modafinil in tablets (Mar. 30, 2011 Trial Tr. at 55:19 – 56:6 (Beach)), and Apotex never requested a contrary construction at any time during *Markman* proceedings. However, even if the asserted claims were to be interpreted (incorrectly, Cephalon's view) to require measurement of the particle size distribution of the bulk API prior to formulation, Apotex's product would nonetheless literally infringe the claims of the '516 Patent. As Cephalon's experts will testify, and as Apotex's expert conceded at trial (Mar. 30, 2011 Trial Tr. 57:17-6, 59:5-60:19 (Beach).), the particle size of modafinil does not change [redacted]. [redacted] Accordingly, Cephalon's

[8] Testing by Cephalon's experts on the remaining three tablet samples of Apotex's modafinil product resulted in 95% cumulative values of 222, 268, and 285 microns. Because Cephalon need not prove that each and every sample tested infringes the '516 Patent, *see, e.g., Paper Converting Machine Co.*, 745 F.2d at 20 ("imperfect practice of an invention does not avoid infringement"), it is not necessary for the Court to reach the question of whether the remaining three tablet samples infringe the '516 Patent under the doctrine of equivalents.

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proof of infringement would be sufficient even if the Court were to find that the relevant measurement is that of the particle size of pre-tabletted modafinil.

2. Apotex's Purported Evidence of Noninfringement Is Fundamentally Flawed

Rather than conduct any testing of its own in response to the particle size testing conducted by Cephalon's experts, Apotex is expected to rely primarily on specifications and data reported in its ANDA as evidence of alleged non-infringement. The particle size specification in Apotex's ANDA [redacted]

As Cephalon's evidence will demonstrate, the particle size measurements in Apotex's ANDA are invalid, inaccurate, and ultimately unreliable. First, Apotex's sampling protocols were flawed. As Cephalon's experts will testify, particle size measurements are only reliable if a representative sample of material is tested. [redacted]

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[redacted][9]

Further, the particle size measurements presented in Apotex's ANDA [redacted]. As described above, it is undisputed that Apotex's manufacturing process [redacted] As Cephalon's expert Dr. Antonietti will explain, this manufacturing step both separates agglomerated particles and results in further reduction of the modafinil particle size. [redacted] Thus, the data presented in Apotex's ANDA with respect to particle size – [redacted] – is insufficient to rebut Cephalon's proof of infringement.

C. APOTEX'S PROPOSED PRODUCT INFRINGES CLAIMS 1-14 AND 16 OF THE '516 PATENT UNDER THE DOCTRINE OF EQUIVALENTS

As discussed above, there is no dispute that the plain language of the claims covers any "pharmaceutical composition," including tablets having modafinil particles the particle size of which falls within the claimed range. However, even if the asserted claims were interpreted

[9] Apotex may also argue that the amended particle size specification for the API in its ANDA, which the FDA found to be "satisfactory," precludes a finding of infringement. However, [redacted]

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(incorrectly, in Cephalon's view) to require measurement of the modafinil particle size before tableting, Apotex's product would infringe under the doctrine of equivalents [redacted] In particular, the modafinil particles in Apotex's tablets perform substantially the same function (a consistent size distribution), in substantially the same way (at least about 95% modafinil particles smaller than about 200 microns), to achieve substantially the same result (a pharmaceutical composition that has consistent potency and safety), [redacted].

II. APOTEX DOES NOT HAVE STANDING TO PURSUE ITS CLAIMS

This Court lacks subject matter jurisdiction over Apotex's '516 Patent claims because there is no justiciable controversy between the parties. *See* Cephalon's Pre-Trial Mem. at 25-29, Dkt. No. 405; Cephalon's Post-Trial Br. at 38-39, Dkt. No. 459. [redacted]. *See*

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Cephalon's Opp. to Apotex's Mot. For Leave to File a Notice of FDA Approval at 2-5, Dkt. No. 467.[10]

[10] In any event, [redacted] would not cure the jurisdictional issue, because a declaratory judgment plaintiff must maintain jurisdiction throughout the pendency of a case, which Apotex has not done. *See* Cephalon's Pre-Trial Mem. at 25-26, Dkt. No. 405 (collecting cases).

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LIST OF WITNESSES

I. EXPERT WITNESSES CEPHALON WILL CALL

1. Dr. Lynn Van Campen, Zeeh Pharmaceutical Experiment Station, School of Pharmacy, 777 Highland Avenue, University of Wisconsin-Madison, Madison, Wisconsin 53705-2222

Dr. Van Campen is expected to testify regarding issues relating to Apotex's infringement of the '516 Patent, including but not limited to the extraction of modafinil API from samples of Apotex's modafinil tablets.

2. Dr. David Bugay, Triclinic Labs, Inc., 1201 Cumberland Avenue, Suite S, West Lafayette, IN 47906

Dr. Bugay is expected to testify regarding issues relating to Apotex's infringement of the '516 Patent, including but not limited to using a Hiac/Royco instrument to perform particle size testing of modafinil API from samples of Apotex's modafinil tablets.

3. Dr. Markus Antonietti, MPI-KG Golm, Research Campus Golm, MPI of Colloids and Interfaces, Dept. of Colloids and Interfaces, Dept. of Colloid Chemistry, 14424 Potsdam, Germany

Dr. Antonietti is expected to testify regarding issues relating to Apotex's infringement of the '516 Patent, including but not limited to methods used in the art to measure particle size of drugs, the product described in Apotex's ANDA, flaws in Apotex's particle size testing, [redacted], the design of the protocol used to extract modafinil API from samples of Apotex's tablets, and the evidence of infringement supplied by the particle size test results generated by Cephalon's other experts.

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II. FACT WITNESSES CEPHALON MAY CALL

1. Bernard Sherman, Apotex, Inc.; 150 Signet Drive, Toronto, Ontario, Canada, M9L 1T9

Cephalon may call by deposition Dr. Sherman to testify on matters primarily relating to laying predicate facts relevant to infringement and Apotex's lack of standing.

2. Bernice Tao, Apotex, Inc.; 150 Signet Drive, Toronto, Ontario, Canada, M9L 1T9

Cephalon may call by deposition Ms. Tao to testify on matters primarily relating to laying predicate facts relevant to infringement and Apotex's lack of standing.

3. Elisabeth Kovacs, Apotex, Inc.; 150 Signet Drive, Toronto, Ontario, Canada, M9L 1T9

Cephalon may call by deposition Ms. Kovacs to testify on matters primarily relating to laying predicate facts relevant to infringement and Apotex's lack of standing.

4. Anna Chow, Apotex, Inc.; 150 Signet Drive, Toronto, Ontario, Canada, M9L 1T9

Cephalon may call by deposition Ms. Chow to testify on matters primarily relating to laying predicate facts relevant to infringement and Apotex's lack of standing.

5. Zhixian Liu, Apotex, Inc.; 150 Signet Drive, Toronto, Ontario, Canada, M9L 1T9

Cephalon may call by deposition Dr. Liu to testify on matters primarily relating to laying predicate facts relevant to infringement and Apotex's lack of standing.

6. Thillairaj Jonathan Lewis, Apotex, Inc.; 150 Signet Drive, Toronto, Ontario, Canada, M9L 1T9

Cephalon may call by deposition Dr. Lewis to testify on matters primarily relating to laying predicate facts relevant to infringement and Apotex's lack of standing.

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7. Yogesh Dandiker, Paddock Labs Inc, 3940 Quebec Avenue N, Minneapolis, MN 55427

Cephalon may call by deposition Dr. Dandiker to testify on matters primarily relating to laying predicate facts relevant to infringement and Apotex's lack of standing.

8. Gordon Fahner, Apotex, Inc., 2400 North Commerce Parkway, Suite 400, Weston, FL 33326

Cephalon may call by deposition Mr. Fahner to testify on matters primarily relating to laying predicate facts relevant to infringement and Apotex's lack of standing.

9. Kiran Krishnan, Apotex, Inc., 2400 North Commerce Parkway, Suite 400, Weston, FL 33326

Cephalon may call by deposition Dr. Krishnan to testify on matters primarily relating to laying predicate facts relevant to infringement and Apotex's lack of standing.

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RELIEF REQUESTED

Cephalon's counterclaim arises under 35 U.S.C. § 271(e)(2)(A), and therefore Cephalon is not seeking money damages at this juncture. Cephalon reserves the right to seek damages or other monetary relief, in the event that the Court finds infringement, if Apotex engages in the commercial manufacture, use, offer to sell, distribution, sale, or importation of modafinil tablets described in Apotex's ANDA prior to the expiration of the '516 Patent. Cephalon seeks:

1. A declaration that the '516 Patent is valid and enforceable;

2. A declaration that a claim or claims of the '516 Patent are infringed by the modafinil tablets described in Apotex's ANDA;

3. A declaration that Apotex Inc.'s submission of the Apotex ANDA and Paragraph IV certification was an act of infringement;

4. A declaration that Apotex's making, using, offering to sell, distributing, selling, or importing the modafinil tablets described in Apotex's ANDA will infringe the '516 Patent;

5. An Order providing that the effective date of any approval of the Apotex ANDA shall be a date which is not earlier than the date of the expiration of the '516 Patent and any regulatory exclusivity period;

6. A permanent injunction enjoining Apotex (including its affiliates and subsidiaries), each of its officers, agents, servants, employees, attorneys, privies, and any and all other persons or entities acting for, on behalf of, or in concert or in participation with any or all of them, from making, using, offering to sell, distributing, selling within the United States, or importing into the United States, the modafinil tablets described in Apotex's ANDA until after the date of the expiration of the '516 Patent, the pediatric exclusivity period, and any other regulatory exclusivity period;

7. A permanent injunction enjoining Apotex and all persons acting in concert with Apotex from seeking, obtaining, or maintaining approval of Apotex's ANDA No. 77-667 until after the date of expiration of the '516 Patent, the pediatric exclusivity period, and any other regulatory exclusivity period; and

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8. An award of costs and reasonable attorneys' fees.

ANTICIPATED LENGTH OF TRIAL

Cephalon anticipates that four to six days will be required for the trial.

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Dated: June 24, 2011

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on the date set forth below the foregoing Defendant Cephalon, Inc.'s Pre-Trial Memorandum – Patent Case (Infringement) (Redacted Version) was electronically filed pursuant to the Court's CM/ECF system, and that the document is available for downloading and viewing from the CM/ECF system. Notice of this filing will be sent to all counsel of record by operation of the CM/ECF system.

/s/ Robert J. Gunther, Jr.
Robert J. Gunther, Jr.

Date: June 24, 2011